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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/816,467 03/26/2001 Laurent Coen 3495.0174-01 7062

22852 7590 09/26/2002

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| EXAMINER |
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CHEN, SHIN LIN

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1632

DATE MAILED: 09/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,467

Applicant(s)

COEN ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 32 and 33, drawn to a method for *in vivo* delivery of a desired composition into human or animal CNS or spinal cord by using a **proteolytic fragment** of tetanus toxin (TT) in association with at least a molecule having a biological function, classified in class 514, subclass 4.
 - II. Claims 12-16 and 27-30, drawn to a method for *in vivo* delivery of a desired composition into human or animal CNS or spinal cord by using a **vector** containing nucleotide sequence encoding hybrid fragment of TT in association with at least a molecule having a biological function, classified in class 435, subclass 69.1.
 - III. Claims 27-30, drawn to a method for *in vivo* delivery of a desired composition into human or animal CNS or spinal cord by using a **cell** containing nucleotide sequence encoding hybrid fragment of TT in association with at least a molecule having a biological function, classified in class 424, subclass 93.2 and 93.21.
 - IV. Claims 17-19 and 21-23, drawn to a hybrid peptide fragment of tetanus toxin comprising a fragment C and a fragment B or a fraction thereof at least 11 amino acid residues, classified in class 530, subclass 300.
 - V. Claims 24 and 31, drawn to a vector or a cell containing a promoter and a nucleic acid coding for the fragment of TT, wherein said nucleic acid is associated with a

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polynucleotide coding for a protein, classified in class 435, subclass 320.1 and 325.

- VI. Claim 25, drawn to a method of treatment of a patient by delivering a composition comprising a **hybrid fragment of TT**, classified in class 514, subclass 4.
- VII. Claim 26, drawn to a method of treatment of a patient by delivering a composition comprising a **vector** expressing hybrid fragment of TT, classified in class 514, subclass 44.

Claims 27-30 link(s) inventions II and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 27-30. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

- 2. The inventions are distinct, each from the other because of the following reasons:

Groups I-III are distinct from each other because they are drawn to methods of using different compositions having different chemical structures, physical properties and biological functions, and requiring separate search: peptides, nucleic acids (vector), and cells. They are

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methods which differ at least in method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. Thus, they are patentably distinct from each other. Similarly, groups VI and VII are patentably distinct from each other.

Groups IV and V are distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: peptides and nucleic acids (vector) or cells. A search for peptides does not require a search for nucleic acids or cells and vice versa. They have different classifications and the search would not be coextensive. Thus, they are patentably distinct from each other.

Groups I-III are distinct from groups VI-VII because they are drawn to methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. A method of treating a disease differs from a method of delivering to a subject. They have different classifications and require separate search. Thus, they are patentably distinct from each other.

Groups IV-V are distinct from groups I-III and VI-VII. Group IV-V and groups I-III and VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.E.P.. § 806.05(h)). In the instant case the hybrid peptide fragment of TT can be used to produce antibody and for purification of said

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antibody. The vectors or cells can be used for producing a recombinant protein or used as an antigen to stimulate immune response in an animal.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 's. chen', located below the printed name.